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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,666	09/29/2003	Mike Clark	PHOE0001-100	5283

35142 7590 09/22/2004

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,666	CLARK, MIKE	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, 25, 30-31 and 41-43, drawn to a method of inhibiting replication of one or more viruses in an individual.

II. Claim 23-24, 30-31, drawn to a method of treating an individual who is suspected of having been exposed to one or more viruses.

III. Claims 26-32, drawn to a method of concurrently treating a tumor and inhibiting replication of one or more viruses in an individual.

IV. Claims 33-38, drawn to a method of modulating nitric oxide levels in an individual.

V. Claim 39, drawn to a method to determine the sensitivity of viral replication to modulating levels of arginine.

VI. Claim 40, drawn to a method to determine the sensitivity of viral replication to modulating levels of nitric oxide.

VII. Claims 44-49, drawn to a method for improving liver function in an individual.

VIII. Claim 50, drawn to a method for identifying an individual as susceptible to arginine deprivation therapy.

IX. Claim 51, drawn to a method of treating one or more viruses in an individual comprising a) determining if the individual is a candidate for arginine deprivation therapy; b) treating the individual with arginine depravation therapy if the individual is a candidate of arginine deprivation therapy; and c)

treating the individual with conventional antiviral treatment if the individual is not a candidate of arginine deprivation therapy.

Inventions I-IX are broadly classified in class 424, subclass 94.1.

2. The inventions are distinct, each from the other because of the following reasons:

In the instant, all the above inventions are related, however, each is patentably distinct from one another. Each of the listed inventions requires a different field of search.

The field of search that would be required for Groups I and IX would be directed to a treating population that has been diagnosed with viral infectivity, whereas, such field of search would not be required for the invention of Group II. The invention of Group II is directed to a different treating population, individuals that are not diagnosed with viral infectivity. A search for the treating population encompassed by the invention of Group I would not overlap with the treating population of Group II, hence, yielding a different field of search. The same is true for the invention of Group III. The treating population of Group III is directed to individuals that are diagnosed with tumors and viral infectivity. This treating population of is different from that of the treating population of Groups I-II. It is recognized that the treating population of Group I and Group II may overlap, however, the level of coextensiveness is not known at the instant; Thus, at the instant, are considered as patentably distinct. Should during examination the Examiner finds that a search for the treating populations of Group I and II overlaps extensively, wherein a serious burden would not be imposed on the Examiner, the Examiner will merge the two Groups into one invention. However, from the search that can be envisioned by the Examiner, a search for one population would not overlap with another population; thereby, requiring a different field of search.

Additionally, the treating population of Group VII is also different from that of Groups I-III. The treating population of Group VII is directed to individuals that diagnosed with irregular liver functions. The listed treating populations are different from one another, thereby requiring a different field of search. A search for one population would not extensively overlap with the other, thereby, rendering the invention patentably distinct from the other.

Should the examination of one treating population be found to overlap with the other during the examination of one of the elected inventions, the Examiner will merge the non-elected invention with the elected invention, wherein the treating population of the non-elected inventions(s) overlaps with the treating population of the elected invention.

The inventions of Groups IV-VI are patentably distinct from that of the inventions of Groups I-V and VII-IX. The inventions of Groups IV-VI are patentably distinct from the inventions of Groups I-V and IX because the two sets of inventions differs in effects. The inventions of Groups I-V and IX are directed to diagnosing or treating individuals, whereas, the inventions of Groups IV-VI are directed to modulating nitric oxide levels, sensitivity of viral replication to modulating arginine levels, and sensitivity of viral replication to modulating levels of nitric oxides. The listed effects are different from one another, thereby requiring a different field of search. A search for one effect would not extensively overlap with the other, thereby, rendering the invention patentably distinct from the other.

Again, should the Examiner finds that the listed effects overlap extensively, the Examiner will appropriately merge the inventions. However, in the instant, the Examiner does not envision an extensive overlap among the listed effects, therefore, a restriction among the inventions is required.

The inventions of Groups I-III, VII and IX are patentably distinct from the invention of Group VIII because the inventions differ in function. The inventions of Groups I-III, VII and IX are directed at treating or improving the well being of a particular population, whereas, the invention of Group VIII is directed to identifying an individual as susceptible to arginine deprivation. The function between the two sets of inventions differs from one another, thereby, requiring a different field of search. A search for one field would not extensively overlap with the other, thereby, rendering the invention patentably distinct from the other.

The invention of Group VIII is patentably distinct from the invention of Groups IV-VI because the inventions differ in effects. The invention of Group VIII is directed to identifying an individual as susceptible to arginine deprivation, whereas the invention of Groups IV-VI is directed at modulating nitric oxide levels, sensitivity of viral replication to modulating arginine levels, and sensitivity of viral replication to modulating levels of nitric oxides. The effect between the two sets of inventions differ from one another, hence, the inventions are patentably distinct from one another.

The invention of Group I is patentably distinct from the invention of Group IX because the inventions differ in their mode of operation and function. The invention of Groups I require the practice of the active method step of administration of a composition, whereas the invention of Group IX requires the practice of the active method step of a) determining if the individual is a candidate for arginine deprivation therapy; b) treating the individual with arginine depravation therapy if the individual is a candidate of arginine deprivation therapy; and c) treating the individual with conventional antiviral treatment if the individual is not a candidate of arginine deprivation therapy. The mode of operation

between the two inventions differ from one another, therefore, the inventions are patentably distinct from one another.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

For Group I, If Applicant elects, Group I, Applicant is required to elect:

a) a compound: antibiotics, antifungals, anti-protozoan drugs, azidovudine, didanosine, d4T, zalcitabine, nevirapine, lamivudine, saquinavir, ritovavir, indinvir, delavirdine, pegylated inteferon-alpha, or ribavirin. All of the above listed species are patentably distinct from one another. The species have different utility and/or lack a significant structural similarity;

b) a linker: succinimide group, an amide group, an amide group, a carbamate group, an ester group, an epoxy group, a carboxyl group, a hydroxyl group, a carbohydrate, a tyrosine group, a cystein group, and a histamine group, and combination thereof. All of the above species are shares a common utility, as linkers, however, the linkers do no share a significant structural similarity; and

c) a amino acid sequence for arginine deiminase; the species are: a set of SEQ ID NOs: 1-4; a set of SEQ ID NOs: 5-10; a set of SEQ ID NOs: 13-14; set of SEQ ID NOs: 15-16; and SEQ ID NO: 17-21, individually.

From the disclosure of the sequences, no significant structural similarity exist among the following sequences or sets of sequences: a set of SEQ ID NOs: 1-4; a set of SEQ ID NOs: 5-10; a set of SEQ ID NOs: 13-14; set of SEQ ID NOs: 15-16; and SEQ ID NO: 17-21, individually.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

If Applicant elects one of the above sets, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species from the elected set of sequences, even though this requirement is traversed. Claim 1 is generic to a plurality of disclosed patentably distinct species, SEQ ID NOs: 1-4; SEQ ID NOs: 5-10; SEQ ID NOs: 13-14; and SEQ ID NOs: 15-16.

For Group II, If Applicant elects Group II, Applicant is required to elect:

a) a linker: succinimide group, an amide group, an amide group, a carbamate group, an ester group, an epoxy group, a carboxyl group, a hydroxyl group, a carbohydrate, a tyrosine group, a cystein group, and a histidine group, and combination thereof. All of the above species are shares a common utility, as linkers, however, the linkers do no share a significant structural similarity.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given above and the search required for any of Groups I-IX is not required for the other, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le

9/20/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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